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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,265	12/21/2001	Rosann Marie Matthews Kaylor	16,976	3108

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/027,265	Applicant(s) KAYLOR ET AL.	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 74 is/are pending in the application.
- 4a) Of the above claim(s) 1 - 40, 42, 47, 52 and 59 - 74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41, 43 - 46, 48 - 51 and 53 - 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/02,5/03,6/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Claims 1 - 40, 42, 47, 52 and 59 - 74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II and Embodiment I, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/10/05.

Information Disclosure Statement

The information disclosure statements filed 9/3/02, 5/9/03, 5/30/03 and 6/4/04 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The information disclosure statements have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 41 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,327,744 to Smith.

In regards to claims 41 and 43, Smith discloses a method for collecting a sample from a test subject, the method including providing a device (12) adapted to capture and retain the sample,

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wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end (16) and a proximal end, the distal end (16) being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end (Col. 2, lines 56 – 58), and a generally tubular outer surface; inserting a finger into the pocket; and contacting the sample with the device (Col. 3, lines 31 – 33). The sample is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings.

4. Claims 41 - 45 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,920,974 to Roth et al.

In regards to claims 41 - 45, Roth et al. discloses a method for collecting a sample from a test subject, the method including providing a device adapted to capture and retain the sample, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open (Col. 3, lines 6 – 9), the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end (Col. 3, lines 9 – 10), and a generally tubular outer surface; inserting a finger into the pocket (Col. 4, lines 40 – 44); and contacting the sample with the device (Col. 4, lines 45 – 46). The sample is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid,

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amniotic fluid, synovial fluid, serous fluid, and bronchial washings. The device includes an interior layer including a substantially liquid impermeable barrier material (Col. 3, lines 13 – 16) that is breathable (Col. 3, lines 8 – 9) to water vapor.

5. Claims 41, 43, 51, 53, 56 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,123,676 to Anapliotis.

In regards to claims 41, 43, 51, 53, 56 and 57, Anapliotis discloses a method for collecting a sample from a test subject, the method including providing a device (Figure 2) adapted to capture and retain the sample, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open (14; Figure 2), the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end (Col. 4, lines 26 – 30), and a generally tubular outer surface; inserting a finger into the pocket; and contacting the sample with the device. The sample is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings. Anapliotis discloses observing a reaction of the sample with an indicator agent on the device without electromechanical assistance (Col. 4, lines 46 – 49). Light is needed to observe the reaction.

6. Claims 41, 43, 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0092843 to Kreiser et al.

7. In regards to claims 41, 43, 46 and 48, Kreiser et al. discloses a method for collecting a sample from a test subject, the method including providing a device adapted to capture and retain

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the sample, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end [0016], and a generally tubular outer surface; inserting a finger into the pocket; and contacting the sample with the device [0017]. The sample is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings. Kreiser et al. discloses analyzing the device using a reader [0019].

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 44, 45, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,123,676 to Anapliotis as applied to claims 41 and 51 above and further in view of U.S. Patent No. 6,114,024 to Forte.

In regards to claims 44, 45, 54 and 55, Anapliotis discloses the device having an interior layer including a barrier material (Col. 4, lines 33 – 34) but fails to disclose the barrier material being breathable to water vapor. Forte teaches a device being formed of a moisture barrier material that is substantially impermeable to liquids yet breathable to water vapor (Col. 1, lines 28 – 37). It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Anaplotis to include a material that is substantially impermeable to liquids yet breathable to water vapor as taught by Forte in order to allow the body of the user to cool naturally (Col. 1, lines 28 – 29).

10. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0092843 to Kreiser et al. as applied to claim 46 above and further in view of U.S. Patent No. 6,114,024 to Forte.

In regards to claims 49 and 50, Kreiser et al. discloses the device having an interior layer including a material but fails to disclose the barrier material being breathable to water vapor. Forte teaches a device being formed of a moisture barrier material that is substantially impermeable to liquids yet breathable to water vapor (Col. 1, lines 28 – 37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Kreiser et al. to include a material that is substantially impermeable to liquids yet breathable to water vapor as taught by Forte in order to allow the body of the user to cool naturally (Col. 1, lines 28 – 29).

11. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,123,676 to Anaplotis as applied to claim 51 above and further in view of U.S. Patent No. 5,660,790 to Lawrence et al.

In regards to claim 58, Anaplotis discloses a method of analyzing a sample including observing the reaction visually (Col. 4, line 48), but fails to disclose observing the reaction using a reader. Lawrence et al. discloses a method of analyzing a sample (Col. 7, line 57 – Col. 8, line 18) including observing the reaction visually or with a reader (Col. 12, lines 14 – 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

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method as disclosed by Anaplotis to include the step of observing the reaction using a reader as taught by Lawrence et al. in order to more precisely quantify the reaction.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 3,672,351 to Ubersax et al. and U.S. Patent No. 4,357,945 to Janko


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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